UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

In re Allergan PLC Securities Litigation	No. 18 Civ. 12089 (CM)

DEFENDANTS' MEMORANDUM OF LAW
IN SUPPORT OF THEIR MOTION TO DISMISS THE
CONSOLIDATED AMENDED CLASS ACTION COMPLAINT

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ALCL	Anaplastic large cell lymphoma
Allergan	Allergan plc and its subsidiaries
ANSM	The French National Agency for Medicines & Health Products Safety
ASR	Alternative Summary Report
BIA-ALCL	Breast-implant-associated ALCL
CAC	Consolidated Amended Class Action Complaint, filed on April 19, 2019, ECF No. 58
Class Period	January 30, 2017 to December 19, 2018 (inclusive of both dates), as defined in ¶ 1 of the CAC
CW	Confidential Witness(es)
Defendants	Individual Defendants together with Allergan plc
FDA	The U.S. Food and Drug Administration
Individual Defendants	Each of Brenton L. Saunders, Maria Teresa Hilado, Matthew M. Walsh, Frances DeSena, Mark Marmur, Paul Bisaro, and William Meury
MAUDE	The FDA's Manufacturer and User Facility Device Experience
MHRA	The United Kingdom's Medicines and Healthcare products Regulatory Agency
Plaintiff	As defined in ¶ 19 of the CAC
PSLRA	Private Securities Litigation Reform Act
TGA	Australia's Therapeutic Goods Administration
WHO	The World Health Organization

PRELIMINARY STATEMENT

On December 18, 2018, a French regulatory authority (the ANSM) unexpectedly asked Allergan to recall certain textured breast implants, noting that the products' CE Mark had not been renewed and that it would be hearing from a committee on the use of breast implants. Following this news, Allergan's share price fell. Three days later, this action was filed, alleging with the benefit of hindsight that Defendants committed fraud by failing to predict the recall.

The CAC doubles down on that theory, alleging—without citing particularized facts—that essentially all of Defendants' statements about Allergan's breast implants and breast implant business during the Class Period were intentionally misleading because they did not disclose a purported "definitive link" between textured implants and ALCL (a rare form of cancer) and did not foresee that Allergan's implants would be recalled from "certain markets" while remaining available in others. At the same time, the CAC relies almost exclusively on information that was publicly available before and throughout the Class Period to plead a claim, including numerous disclosures by Defendants openly informing investors (and health care practitioners and patients) of a potential ALCL association. While Allergan takes patient safety and product quality very seriously, the CAC presents nothing more than classic fraud-by-hindsight for a securities claim, predicated on one regulator's unexpected recall request that expressly was not based on new scientific evidence—let alone evidence that Allergan allegedly knew and kept from the public.

The CAC should be dismissed for several reasons. First, the CAC fails to adequately allege any misstatements or omissions. Critically, the CAC fails to plead any facts, let alone particularized facts, that there is a "definitive link" between Allergan's implants and ALCL—indeed, as the very documents cited in the CAC state, none has been established—or that the ANSM's recall request could have been predicted. Even if the CAC had adequately pleaded

such facts, which it did not, its claims would still fail because it routinely relies on fraud-by-hindsight, challenges nonactionable statements of puffery, and overwhelmingly relies on sources that were widely reported before and throughout the Class Period. Defendants cannot be held liable for failing to disclose such information, which was readily accessible to the public. See Bettis v. Aixtron SE, 2016 WL 7468194, at *12 (S.D.N.Y. Dec. 20, 2016) (McMahon, J.).

Second, the CAC fails to state a claim because it does not raise a "strong" inference of scienter. Rather than identifying specific, undisclosed information contradicting Defendants' disclosures when made, the CAC relies on conclusory assertions and publicly available sources to claim—with the benefit of hindsight—that Defendants must have known their statements were false. The CAC's further reliance on stock sales by two Individual Defendants fares no better, as the overwhelming majority of Individual Defendants made no sales, and the few identified sales are not remotely suspicious. In short, the far more compelling inference is that Defendants possessed honestly held optimism about their business, were not aware of any "definitive link" to ALCL, believed they made adequate disclosures of any possible association, and were surprised by a recall request that was not based on new scientific evidence.

Third, Plaintiff cannot plead reliance. In light of the extensive publicly available sources cited in the CAC, Plaintiff could have discovered at the time of its investments the precise allegations it now asserts are sufficient to state a claim.

Finally, the CAC fails to plead loss causation. It points only to losses after the ANSM recall request, which was not based on new scientific data and did not reveal that Defendants' prior statements were false when made. See Fort Worth Emps.' Ret. Fund v. Biovail Corp., 615 F. Supp. 2d 218, 229 (S.D.N.Y. 2009) (McMahon, J.) (no loss causation where decline "was caused by the [FDA]'s failure to approve the drug—not by any 'corrective' disclosure").

FACTUAL BACKGROUND

I. Allergan's Business

Allergan is a global pharmaceutical company focused on developing, manufacturing, and bringing to market a wide range of pharmaceutical and medical products, including therapeutics for central nervous system disorders, eye care, women's health, and gastroenterology. CAC ¶ 2; Ex. 14 at 3 (cited CAC ¶¶ 132-36, 181).[1] For over 30 years, Allergan and its predecessors have manufactured and sold breast implants for post-mastectomy reconstructive surgery and cosmetic augmentation. CAC ¶¶ 2, 33. Some of these implants have smooth outer-shells, while others have textured outer-shells. Id. ¶ 49. Each of these types has a different benefit-risk profile, and all are subject to numerous regulatory requirements by regulators across the globe, including the FDA, ANSM, MHRA, TGA, and Health Canada. Id. ¶¶ 11, 35, 36, 67, 80-81, 174, 178.

II. Public Awareness About A Potential Association Between Textured Implants And ALCL Before The Class Period

ALCL is a rare type of non-Hodgkin lymphoma. Id. ¶ 63. For decades, researchers, regulators, and manufacturers, including Allergan, have studied the disease to better understand and increase awareness of BIA-ALCL. Id. ¶¶ 64-67, 176-77. The first reported case of BIA-ALCL occurred in 1997. Id. ¶ 64. The disease "garnered more attention" during the following decade after multiple studies were published about ALCL, including a November 2008 study that identified 11 individuals with implants who were diagnosed with ALCL and "found a positive association between breast implants and . . . ALCL." Id. ¶¶ 64-65.

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[1] All references to "Ex. __" are to the exhibits attached to the Declaration of Anna F. Connolly. "On a motion to dismiss, the Court 'may consider any written instrument attached to the complaint, statements or documents incorporated into the complaint by reference, legally required public disclosure documents filed with the SEC, and documents possessed by or known to the plaintiff and upon which it relied in bringing the suit.'" Bettis, 2016 WL 7468194, at *1 n.1. The Court may also consider certified translations of foreign language documents. See, e.g., Negrin v. Kalina, 2010 WL 2816809, at *2 n.4 (S.D.N.Y. July 15, 2010).

In January 2011, the FDA issued a report titled "Anaplastic Large Cell Lymphoma (ALCL) In Women with Breast Implants," which "review[ed the] scientific literature published from January 1997 through May 2010" and "identified 34 unique cases of ALCL." Ex. 1 at 5 (cited CAC ¶ 66 & n.12). The FDA concluded at that time "that there is a possible association between breast implants and ALCL." Id. at 11 (emphasis added). The FDA further noted that it was "not possible to identify a specific type of implant associated with a lower or higher risk of ALCL," but "ALCL has been found more frequently in association with breast implants having a textured outer shell rather than a smooth outer shell." Id. In February 2011, the MHRA likewise warned, "[t]here is uncertain evidence that women with breast implants may have a very small but increased risk of [ALCL]." Ex. 8 at 1 (cited CAC ¶ 67 & n.13).

In May 2016, the WHO reported that "[a] number of studies in recent years have identified a unique form of ALK¯ALCL arising in association with breast implants designated as [BIA-ALCL]," but "[t]he factors leading to progression have not been delineated." Ex. 12 at 2384 (cited CAC ¶¶ 6, 79, 122 & n.20). Thus, as of January 30, 2017—the first day of the Class Period—an article relied on by the CAC stated the FDA was "not prepared to say that [] textured breast implants . . . cause lymphoma." Ex. 13 at 3 (cited CAC ¶¶ 8-9, 83-86, 125-26 & n.23).

III. Allergan's Disclosures Concerning The Potential Association Between ALCL And Textured Implants Both Before And Throughout The Class Period

Over the past decade, Defendants regularly disclosed the possible association between ALCL and textured breast implants, as well as the related risks of regulatory action and an impact on earnings. Since 2011, Allergan has disclosed in each of its annual SEC filings reports about "a possible association" between breast implants and ALCL. See Exs. 2, 3, 5, 6, 9, 11, 14, 20 (cited CAC ¶¶ 148-53), 29. For years, Allergan further disclosed that "the manufacture and sale of breast implant products has been and continues to be the subject of a significant number

of product liability claims due to allegations that the medical devices cause disease or result in complications, rare lymphomas and other health conditions." See, e.g., Exs. 2, 3, 5. These disclosures also repeatedly warned that "[n]egative publicity," including "reports that have suggested a possible association between [ALCL] and breast implants," "whether accurate or inaccurate" could "result in product withdrawals and cause [Allergan's] stock price to decline." Ex. 14 at 29; see also, e.g., Exs. 3, 5. Allergan also cautioned investors in annual filings that "[t]he FDA and other regulatory authorities also monitor adverse event reports" and "may take action . . . including . . . withdrawal of a product from the market." Ex. 3 at 24; see also, e.g., Exs. 5, 6.

IV. Allergan's CE Mark for Textured Breast Implants Is Not Renewed But The Implants Remain Available in Other Markets

Allergan's breast implants historically received their CE certificates in Europe from GMED, a French notified body for the European Directives covering medical devices. See Ex. 24 (cited CAC ¶¶ 11, 164, 168); see also Ex. 26.[2] Allergan is required to renew its CE Mark every five years. See Ex. 24. In December 2018, GMED advised Allergan that its CE Mark for textured breast implants would not be renewed. See id.; see also Ex. 26. The CE Mark expired by December 17, 2018. See Ex. 24; see also Ex. 26. On December 18, 2018, ANSM—noting GMED's non-renewal—requested that Allergan recall its textured breast implants. Ex. 24; see CAC ¶¶ 11, 164.

Notably, the ANSM's recall request was not based on any new safety information related to implants—indeed, it did not cite any new scientific evidence or even mention a "link" (let alone a "definitive link") between the implants and ALCL. Ex. 24. To the contrary, the request stated that the ANSM had "not as yet identified any immediate health risk to women carrying

[2] See generally http://www.lne-gmed.com/en/services/ce-marking.asp.

[textured] implants," and noted that the ANSM would be hearing from an "expert committee" about the use of implants in February 2019. Id. The CAC mischaracterizes the recall request, claiming that in it the ANSM "stat[ed]" that Allergan's implants "have been linked to a rare form of cancer." CAC ¶¶ 11, 164. The recall request said no such thing. See Ex. 24.

Subsequently, during the ANSM's conference on BIA-ALCL in February 2019, the European Taskforce on BIA-ALCL submitted the collective view of all Member States except France, that "[s]cientific proof of causal relationship [between BIA-ALCL and implants] has not been established and the cause and the mechanism for the development of BIA-ALCL is yet to be determined." Ex. 28 § 1. As such, the Taskforce concluded "there is insufficient scientific evidence to limit the use of textured breast implants." Id. § 10. Similarly, on May 2, 2019, the FDA announced that it was not ordering a recall of textured implants in the United States, stating, "[a]t this time, the FDA does not believe that, on the basis of all available data and information, the device meets the banning standard set forth in the Federal Food, Drug and Cosmetic Act." Ex. 35 at 5. The FDA acknowledged that "[a] few of our international counterparts have started to initiate actions to ban or restrict sales of some textured breast implants," but stated that FDA action "must be based on scientific data" and the agency was "still investigating the cause of the association" between textured implants and BIA-ALCL. Id.

V. The Filing of This Action And The CAC

The initial complaint in this action was filed on December 21, 2018, just days after the ANSM recall request. Dkt. 6. Plaintiff filed the CAC on April 19, 2019, alleging that Defendants "failed to disclose that textured breast implants manufactured by Allergan were definitively linked to ALCL," as well as other supposed information concerning Allergan's research, reporting, and patient warnings relating to the implants. CAC ¶ 10 (emphasis added).

ARGUMENT

To survive a motion to dismiss, "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). The securities fraud claims alleged here are further subject to the heightened pleading requirements of Rule 9(b) and the PSLRA, which require "that securities fraud complaints 'specify' each misleading statement; that they set forth the facts 'on which [a] belief' that a statement is misleading was 'formed'; and that they 'state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.'" Merrill Lynch, Pierce, Fenner & Smith Inc. v. Dabit, 547 U.S. 71, 81-82 (2006).

To state a Section 10(b) claim, Plaintiff must allege Defendants "(1) made misstatements or omissions of material fact; (2) with scienter; (3) in connection with the purchase or sale of securities; (4) upon which plaintiff relied; and (5) that plaintiffs' reliance was the proximate cause of their injury." Lentell v. Merrill Lynch & Co., 396 F.3d 161, 172 (2d Cir. 2005).

I. THE CAC DOES NOT ADEQUATELY PLEAD ANY ACTIONABLE MISSTATEMENT OR OMISSION

A. Plaintiff Does Not Adequately Plead A "Definitive Link" Between Breast Implants And ALCL, And Any Association Was Publicly Disclosed

Plaintiff's main theory is that a broad range of Defendants' disclosures—essentially any statements touching on their breast implant products or business—were misleading because they omitted an alleged "definitive link" (a term Plaintiff appears to have penned) between Allergan's textured breast implants and ALCL. See CAC ¶¶ 10(i)-(ii), 126, 128, 130, 132-35, 138, 140, 142, 144, 146, 149-51, 155, 157, 159, 162. This theory fails for three independent reasons.

First, the CAC fails to plead particularized facts demonstrating that a "definitive link" between textured implants and ALCL exists. Tellingly, the CAC is filled with references to literature about ALCL but does not quote a single source identifying any "definitive link." Not

only does Plaintiff fail to identify a scientific consensus that a "definitive link" exists, but the FDA refers to an "associat[ion]" and "hypotheses that propose a link." Ex. 33 at 5, 7 (cited CAC ¶ 172). Indeed, the CAC cites studies and other disclosures published during and after the Class Period referring to a possible association—not a "definitive link"—between textured implants and ALCL. See, e.g., Ex. 31 at 6 (Health Canada statement that "a definite causal link could not be established" (cited CAC ¶ 174)).[3] Plaintiff's conclusory assertions that a "definitive link" exists are affirmatively rebutted by the very sources on which it relies and thus are insufficient to plead a misstatement or omission at the time of any challenged statement. See In re Bristol-Myers Squibb Sec. Litig., 312 F. Supp. 2d 549, 555 (S.D.N.Y. 2004) ("The court need not accept as true an allegation that is contradicted by documents on which the complaint relies.").

The most Plaintiff musters is a single statement from the French National Cancer Institute that there is a "clearly established link between the occurrence of [ALCL] and the presence of a breast implant." Ex. 10 at 3 (cited CAC ¶ 77). Putting aside that this statement was publicly disseminated almost two years before the Class Period and Allergan had no duty to disclose it, see infra, the study found only a link between ALCL and breast implants generally; although omitted by Plaintiff, the report said it was still "necessary to explore the potential association between macrotexturing of the implant and the occurrence of BIA-ALCL." Ex. 10 at 3 (emphasis added). The statement cited by Plaintiff was also highly caveated—acknowledging that the data showing the frequency of ALCL was "too low" to "identify other risk factors

[3] See also Ex. 16 at 3 (MHRA confirmed "no definitive evidence of an association with ALCL and any specific make or model of breast implant" and "stressed it was not possible to confirm that the cases of cancer were caused by the implants" (cited CAC ¶ 98 & n.30)); Ex. 19 at 8 (JAMA reports various considerations "preclude reliable conclusions on associations between implant types or vendors and the risk of developing BIA-ALCL" (cited CAC ¶ 103 & n.34)); Ex. 27 at 30 ("associations need to be further analyzed with patient-level data to provide conclusive evidence" (cited CAC ¶ 112 & n.41)). See infra n.7.

associated with the occurrence of this disease," "subject to many biases," and marred by "missing data." Id. In any event, the statement represents the opinion of a single entity at a discrete point in time without any suggestion that it represented the prevailing wisdom then, let alone during the Class Period two years later. To the contrary, the CAC cites many other sources that concluded no such link had been clearly established. See supra n.3; infra & n.7.[4]

Similarly, Plaintiff challenges a statement addressing the "safety profile" of Allergan's implants, CAC ¶¶ 159-61, not because anything in it is affirmatively false, but because it—while citing to several studies—"fails to cite to, and acknowledge" certain additional studies that purportedly establish that BIA-ALCL "is exclusively found in textured implants" and that "Allergan's implants are associated with more cases than any other type of textured implant." Id. ¶ 161. Plaintiff, however, does not identify a single one of those "additional studies"—which presumably were publicly available—containing such information, and otherwise cites public information contradicting both points. See, e.g., Ex. 19 at 8 (various considerations "preclude reliable conclusions on associations between implant types or vendors and the risk of developing BIA-ALCL"); Ex. 33 at 15 (identifying 24 instances of reports of BIA-ALCL from individuals with smooth implants); see also Ex. 35 at 5 ("there are known cases [of BIA-ALCL] in women with smooth-surface breast implants" (emphasis added)). Nor does Plaintiff explain how the contents of such studies rendered Allergan's statements false.

Second, Plaintiff cannot rely on the subsequent recall of Allergan's textured breast implants in Europe to plead that Allergan's prior statements about those products and its implant business were false when made. See CAC ¶ 10(i)-(iii). Plaintiff's reliance on the recall

[4] While the CAC asserts that ANSM's recall request states that implants "have been linked to a rare form of cancer," CAC ¶¶ 11, 164, the recall request says no such thing, see Ex. 24.

request—which followed and referenced GMED's non-renewal of the CE Mark—is classic fraud-by-hindsight: The CAC does not plead any facts, let alone particularized facts, that the recall in certain markets (with the breast implants remaining available in other markets) could have been predicted during the Class Period. This is particularly true given that the CE Mark had previously been successfully renewed several times; the CAC contains no facts indicating that Defendants were privy to any information that the CE Mark would not be renewed again; and ANSM's recall request did not cite any new scientific evidence. Moreover, to the extent the CAC suggests that Allergan should have conservatively predicted that its textured breast implants would be recalled by a particular regulator, Defendants had no duty to take a gloomy view of the prospects of their products or to predict future negative regulatory actions. See Shields v. Citytrust Bancorp, Inc., 25 F.3d 1124, 1129 (2d Cir. 1994). In any event, Allergan explicitly disclosed this very risk.[5] See supra Factual Background III.

Finally, Plaintiff's claims also fail because Allergan and others repeatedly disclosed—before and during the Class Period—risks in connection with a possible association between textured implants and ALCL. The CAC itself cites many of Allergan's disclosures, including:

- Allergan's statement that reports "have suggested a possible association between [ALCL] and breast implants." Ex. 14 at 29; Ex. 20 at 29;
- Allergan's warning that, "[o]ver the past 15 years, there has been scientific discussion about cases of ALCL being reported very rarely in women who have also had breast implant procedures." Ex. 21 (cited CAC ¶¶ 159-60);
- Allergan's disclosure that it "is and has been fully committed to investing in and supporting work to further understanding and increasing awareness of [BIA-ALCL]." Ex. 23 at 7 (cited CAC ¶¶ 115-16, 162);

[5] Since 2011, Allergan has repeatedly disclosed in its Form 10-Ks the risk of product recalls or withdrawals, including based on "negative publicity" or regulator conduct. See supra Factual Background III; see Bettis, 2016 WL 7468194, at *13-14 (cautionary language tailored to relevant language insulates defendants from liability).

- Allergan acknowledging that a "possible association has been identified between breast implants and the rare development of [ALCL]" and that "ALCL has been reported globally in patients with an implant history that includes [A]llergan's and other manufacturers' breast implants." Ex. 4 at 1 (cited CAC ¶ 121 & n.45); and

- Allergan stating that "BIA-ALCL has been reported in patients with textured breast implants from all manufacturers." Ex. 13 at 7.[6]

These disclosures by Allergan of the very information alleged to be omitted defeat any claim of securities fraud. See Bettis, 2016 WL 7468194, at *11 (granting motion to dismiss where defendant "made exactly the disclosures that Plaintiff claims were withheld from investors").

Similarly, the CAC cannot plead a misstatement by citing numerous disclosures by governmental agencies, physicians, and others before and during the Class Period about the possible association between textured implants and ALCL.[7] As this Court held in Bettis, such an approach fails to state a claim because "[i]t has long been established that 'where information is equally available to both parties, a defendant should not be held liable to the plaintiff under the securities laws for failure to disclose.'" Id. at *12-13 (dismissing claim where "[t]he only attempt Plaintiff ma[de] to support the notion that [the defendant] knew or should have known about the [issue] is to point to the very articles that reported the news").

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[6] Allergan also repeatedly disclosed the potential association between ALCL and textured breast implants in disclosures not cited by Plaintiff. See, e.g., Ex. 2 at 39 ("The manufacture and sale of breast implant products has been and continues to be the subject of a significant number of product liability claims due to allegations that the medical devices cause disease or result in complications, rare lymphomas and other health conditions . . . . Historically, other breast implant manufacturers that suffered such claims in the 1990's were forced to cease operations or even to declare bankruptcy.").

[7] See, e.g., Ex. 1 at 11 ("there is a possible association between breast implants and ALCL"); Ex. 8 at 1 (there is "uncertain evidence that women with breast implants may have a very small but increased risk of [ALCL] – none reported in the UK"); Ex. 12 at 2384 ("A number of studies in recent years have identified a unique form of ALK^{-}ALCL arising in association with breast implants"); Ex. 33 at 5, 7 (noting "associat[ion]" and stating "[t]here are hypotheses that propose a link between breast implant texturing and BIA-ALCL").

B. The CAC's Allegations About Allergan's Santa Barbara Facility, Adverse Event Reports, And Consumer Complaints Do Not Plead False Statements

Plaintiff further asserts that statements concerning Allergan's efforts to "help advance the knowledge of . . . BIA-ALCL" were misleading because "Allergan shut down its Santa Barbara facility, which was the center for breast implant research and development." See CAC ¶¶ 127, 137, 141, 154, 158, 163. But the closing of that facility was publicly disclosed well before the Class Period, see, e.g., Ex. 7 at 15, and thus cannot establish that Defendants misled the public.

Moreover, the CAC does not contain any particularized facts indicating that the publicly announced closure of this facility before the Class Period resulted in Allergan not performing any research regarding ALCL during the Class Period. Indeed, the single confidential witness on whom the CAC relies for this theory (CW2) was not even employed during most of the Class Period, CAC ¶ 30, and thus cannot speak to the research done at the relevant time. See In re Wachovia Equity Sec. Litig., 753 F. Supp. 2d 326, 352 n.17 (S.D.N.Y. 2011). And, any contention that no research was done during the Class Period is belied by the very sources on which Plaintiff relies, which state that Allergan relocated some of its Santa Barbara operations elsewhere and also "actively work[ed] to help advance knowledge of this disease" by conducting its own research, funding external research, conducting surgeon education meetings and webcasts, and partnering with other organizations (including the American Society of Plastic Surgeons and the International Society of Aesthetic Plastic Surgery) to distribute BIA-ALCL educational materials. Ex. 7 at 15; Ex. 13 at 7-8; Ex. 34 at 19-20 (cited CAC ¶¶ 176-79). Indeed, the CAC itself cites ALCL studies funded by Allergan, relies on information from "Allergan's post-approval studies," and discusses at length a recent presentation describing Allergan's "independent research" on ALCL. CAC ¶¶ 87, 176-79.

For similar reasons, Plaintiff's threadbare assertions that Allergan submitted at least one case of "possible" BIA-ALCL through an ASR—a form that allows multiple adverse events to be reported in a single submission—and thus allegedly "contradict[ed] [its] statements" about complying with FDA reporting guidelines and that its products "undergo . . . extensive government regulatory clearance or approval process[es]" fail. See, e.g., id. ¶¶ 10(vi)-(vii), 127, 133, 137, 141, 151, 154, 163. Plaintiff pleads no facts indicating that the filing of that one ASR (which they do not even cite), or any other filings by Allergan, were not in compliance with FDA regulations. To the contrary, the very article on which Plaintiff relies—which nowhere mentions Allergan or breast implants—makes clear that the filing of ASRs was permissible and even encouraged by the FDA to reduce "redundant paperwork" and "'allow[] the FDA to more efficiently review adverse events.'" Ex. 30 at 3, 7 (cited CAC ¶ 121 & n.44); see Oran v. Stafford, 226 F.3d 275, 284 (3d Cir. 2000) (affirming dismissal of complaint concerning product recall where "plaintiffs do not allege that [defendant] withheld any information that it was legally required to disclose to the FDA"). At bottom, Plaintiff's assertions that Defendants should not have used an ASR reflect its disagreement with the FDA's judgment in permitting those reports, but do not state a claim of securities fraud.[8]

Likewise, the CAC's repeated assertions that Defendants' statements were misleading because, "as detailed in various consumer complaints, Allergan was not appropriately advising patients of the risks associated with . . . BIA-ALCL," see CAC ¶ 10(viii), 127, 137, 141, 154,

[8] Plaintiff misleadingly alleges that "Allergan submitted a significant number of adverse event reports under incorrect manufacturer names such as 'Costa Rica' or 'Santa Barbara' instead of 'Allergan.'" CAC ¶ 120. In fact, the adverse event report cited by Plaintiff does not omit the name "Allergan," but instead identifies the specific Allergan entity that manufactured the device, "Allergan (Costa Rica)," as required by the FDA. Moreover, Plaintiff fails to mention that this adverse event report did not confirm a case of ALCL. Ex. 4 at 1 ("pathological markers confirming alcl have not been received").

158, 163, are entirely conclusory. The CAC nowhere cites these complaints, much less provides details about what they allege or whether they adequately show patients were not appropriately advised of any risks, concern the relevant time period, or are sufficient in number to be material. See Bettis, 2016 WL 7468194, at *9. Even more fundamentally, the CAC fails to identify any statement by Defendants that would be rendered false by this allegation, such as one guaranteeing every patient would consider herself appropriately advised of BIA-ALCL risks.

C. Many of The Alleged Misstatements Are Puffery Or Were Indisputably True

Plaintiff's claims about many of the challenged statements must also be dismissed because those statements are mere "expressions of puffery and corporate optimism [that] do not give rise to securities violations." Rombach v. Chang, 355 F.3d 164, 174 (2d Cir. 2004). Such statements of puffery are not actionable because they are simply "too general," City of Pontiac v. UBS AG, 752 F.3d 173, 183 (2d Cir. 2014), for an "investor [to] take such statements seriously," ECA, Local 134 IBEW v. JP Morgan Chase Co., 553 F.3d 187, 206 (2d Cir. 2009).

Here, many of the CAC's challenged statements are precisely the type of vague and optimistic statements that courts routinely dismiss as puffery:

- Statements Allergan had a "robust" surveillance process, CAC ¶¶ 8, 83, 125, 127, or "a very large robust business" with implants, id. ¶¶ 128-129 (emphases added).[9]
- Statements Allergan was "number one" and a "Number 1 player in breast implants," id. ¶¶ 130-31, 138-39, 181, a "[w]orld leader," id. ¶ 138, "markets a portfolio of leading brands and best-in-class products," id. ¶ 149, and that its implants are "the best" or a "key promoted product," id. ¶¶ 132, 137 (emphases added).[10]

[9] See In re Biogen Inc. Sec. Litig., 193 F. Supp. 3d 5, 41-42 (D. Mass. 2016) ("core business . . . is robust"), aff'd, 857 F.3d 34 (1st Cir. 2017); In re Gentiva Sec. Litig., 932 F. Supp. 2d 352, 370 (E.D.N.Y. 2013) (compliance program "robust"); In re ANZ Banking Grp. Ltd. Sec. Litig., 2009 WL 4823923, at *11 (S.D.N.Y. Dec. 14, 2009) (company had "robust process").

[10] See Gregory v. ProNAi Therapeutics Inc., 297 F. Supp. 3d 372, 399 (S.D.N.Y. 2018) (company was "a leader"); In re Gentiva, 932 F. Supp. 2d at 370 (program was "best-of-class"); In re USEC Sec. Litig., 190 F. Supp. 2d 808, 822 (D. Md. 2002) (company was "world leader").

- Statements the business had a "strong quarter" or "has done well," id. ¶¶ 142, 144-45, or that sales were "exceptionally strong," id. ¶ 146 (emphases added).[11]

Separately and additionally, Plaintiff does not plead any facts indicating that these statements were not true. These statements are therefore neither false nor give rise to a duty to predict that future regulatory action could threaten these facts in the future. See Biovail, 615 F. Supp. 2d at 230 (disclosure containing "historical fact" that FDA accepted application for review, which was "not alleged to be false," is not actionable for failure to predict FDA's future response).

II. THE CAC FAILS TO PLEAD A STRONG INFERENCE OF SCIENTER

Scienter requires "an intent to deceive, manipulate or defraud." Ernst & Ernst v. Hochfelder, 425 U.S. 185, 193 n.12 (1976). To establish scienter, a plaintiff must allege specific facts "(1) showing that the defendants had both motive and opportunity to commit the fraud or (2) constituting strong circumstantial evidence of conscious misbehavior or recklessness." ATSI Commc'ns, Inc. v. Shaar Fund, Ltd., 493 F.3d 87, 99 (2d Cir. 2007). For these purposes, recklessness is "conscious recklessness—i.e., a state of mind approximating actual intent, and not merely a heightened form of negligence." S. Cherry St., LLC v. Hennessee Grp., 573 F.3d 98, 109 (2d Cir. 2009). Under the PSLRA, a plaintiff must raise a "strong inference" of scienter, meaning one that is "cogent and at least as compelling as any opposing inference of nonfraudulent intent." Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 314 (2007). The CAC does not come close to satisfying these standards.

A. The CAC Does Not Allege Motive Or Opportunity To Defraud

Motive and opportunity may be pleaded if a plaintiff alleges "suspicious" insider sales at the time the seller allegedly "withheld material information from the investing public." Koplyay

[11] See In re Biogen, 193 F. Supp. 3d at 41-42 ("remains strong"); Pearlstein v. BlackBerry Ltd., 93 F. Supp. 3d 233, 241 (S.D.N.Y. 2015) ("exceptional technology"); In re Citigroup Inc. Sec. Litig., 987 F. Supp. 2d 377, 381, 385 (S.D.N.Y. 2013) ("strong capital position").

v. Cirrus Logic Inc., 2013 WL 6233908, at *5 (S.D.N.Y. Dec. 2, 2013) (McMahon, J.). The suspiciousness of a sale turns on a number of factors, including "the number of insider defendants selling," "the percentages of holdings sold," "whether sales occurred soon after statements that defendants are alleged to have known were misleading," "whether sales occurred shortly before corrective disclosures," and "whether sales were made pursuant to trading plans, such as Rule 10b5-1 plans." Id. Plaintiff fails to make such a showing.

1. Five of Seven Individual Defendants Made No Sales, Undermining Any Inference of Scienter

As an initial matter, five of the seven Individual Defendants—Saunders (Chairman, President, and CEO); Hilado (former CFO); Walsh (current CFO); DeSena (a Vice President); and Marmur (an Associate Vice President), CAC ¶¶ 21-25—are not alleged to have engaged in any stock sales during the Class Period. "This reason alone requires" dismissal of the claims against these defendants, Oran, 226 F.3d at 289, and also "undermines plaintiff['s] claim" that the limited number of sales by two Defendants raises an inference of scienter as to all Defendants, Acito v. IMCERA Grp., 47 F.3d 47, 54 (2d Cir. 1995).[12]

2. The CAC Fails To Plead That Bisaro's Sale Was Suspicious

With respect to Bisaro, Plaintiff alleges that the timing of his single stock sale was "suspicious" because it occurred a little over two weeks after he supposedly "touted on a February 13, 2017 conference call that Allergan's breast implant business was 'number one'"—a statement actually made by Meury, CAC ¶ 130—and approximately one week after Allergan filed its 2016 Form 10-K. Id. ¶ 181. These allegations fail for numerous reasons:

- Bisaro did not individually make any of the challenged statements and is not alleged to have had any specific role in controlling the challenged statements, and thus lacked an opportunity to defraud. See Russo, 777 F. Supp. 2d at 518 (no opportunity where

[12] See also Russo v. Bruce, 777 F. Supp. 2d 505, 517 (S.D.N.Y. 2011); In re Gildan Activewear, Inc. Sec. Litig., 636 F. Supp. 2d 261, 271-72 (S.D.N.Y. 2009).

"Complaint does not attribute a single alleged misstatement to [defendant]" or "plead facts suggesting [defendant] . . . exerted any control over [the] public statements").

- Plaintiff does not even attempt to plead particularized facts indicating that Bisaro—a non-employee director during the Class Period, CAC ¶ 26—had knowledge of undisclosed facts at the time of his sale. See Acito, 47 F.3d at 54 (sale of stock by former officer who had been "outside director during most of the class period" does not give rise to strong inference of scienter); Russo, 777 F. Supp. 2d at 517-18.

- Bisaro made only a single sale just one month into the 23-month Class Period, and almost two years before the purported corrective disclosure. See City of Royal Oak Ret. Sys. v. Juniper Networks, Inc., 880 F. Supp. 2d 1045, 1069 (N.D. Cal. 2012) (no scienter where individual "made only one sale during the entire Class Period"); City of Brockton Ret. Sys. v. Shaw Grp., 540 F. Supp. 2d 464, 475-76 (S.D.N.Y. 2008) (McMahon, J.) (sale more than ten weeks before end of class period not "strongly suspicious"); McCasland v. FormFactor Inc., 2008 WL 2951275, at *10 (N.D. Cal. July 25, 2008) (no scienter with respect to sale early in class period).

- Bisaro's sale was made shortly after the filing of Allergan's 2016 Form 10-K, which was the first time Bisaro was permitted to sell shares after stepping down from his executive role at Allergan on December 31, 2016. CAC ¶¶ 26, 181; see Local No. 8 IBEW Ret. Plan v. Vertex Pharma. Inc., 140 F. Supp. 3d 120, 136-37 (D. Mass. 2015) (individual selling shares when leaving company is "not unusual"); City of Taylor Gen. Emps. Ret. Sys. v. Magna Int'l Inc., 967 F. Supp. 2d 771, 799 (S.D.N.Y. 2013) ("most plausible inference is that [defendant] sold his stock as a 'normal and expected' consequence of his retirement"); In re Party City Sec. Litig., 147 F. Supp. 2d 282, 312 (D.N.J. 2001) ("Trading following public announcements simply evidences compliance with the securities laws. . . . Indeed, insiders are only permitted to trade in a 'window' after a public announcement is made.").

- Bisaro sold only 16.4% of his holdings. Ex. 15.[13] See Koplyay, 2013 WL 6233908, at *5 (sales up to 14% "represented only a small fraction of . . . total beneficial ownership"); Gildan, 636 F. Supp. 2d at 271 (sales up to 22.5% of total holdings were "relatively small in volume compared to overall holdings"); McCasland, 2008 WL 2951275, at *10 (no scienter with respect to sale of 17% of shares).

Thus, Plaintiff's allegations as to Bisaro's purported motive are insufficient and instead reflect an apparent attempt to name Bisaro—the only non-executive director named out of eleven on the Board at the time—as a defendant solely because of his single stock sale.

[13] Courts routinely consider Form 4s in considering allegations concerning motive and opportunity. See In re Sina Corp. Sec. Litig., 2006 WL 2742048, at *11 (S.D.N.Y. Sept. 26, 2006); Bristol-Myers, 312 F. Supp. 2d at 561 n.6; Oran, 226 F.3d at 289.

3. The CAC Fails To Plead That Meury's Sales Were Suspicious

The CAC fails to raise any, let alone a strong, inference of scienter based on Meury's sales:

- ***December 1, 2017 sale***. Meury's sale of 11,807 shares of Allergan stock on December 1, 2017 was not "suspicious" because it took place an entire month after a purported misstatement. CAC ¶¶ 181-182; see, e.g., In re Lululemon, 14 F. Supp. 3d 553, 586 n.24 (S.D.N.Y. 2014) (timing of stock sale not suspicious when sale was over two weeks after challenged statement), aff'd, 604 F. App'x 62 (2d Cir. 2015). Regardless, the options Meury exercised and sold at this time were set to expire four days later, on December 5, 2017. See Ex. 18. As numerous courts have recognized, exercising "expiring options . . . does not . . . demonstrate a motive to defraud." City of Taylor, 967 F. Supp. 2d at 799-800; see also N. Collier Fire Control v. MDC Partners, Inc., 2016 WL 5794774, at *20 (S.D.N.Y. Sept. 30, 2016).

- ***February 14, 2018 and May 17, 2018 sales.*** Meury's two other stock sales were likewise not suspicious because they were made pursuant to a Rule 10b5-1 plan entered into November 16, 2017—three and six months before the sales. CAC ¶¶ 183-84; see Glaser v. The9, Ltd., 772 F. Supp. 2d 573, 592 (S.D.N.Y. 2011) ("[I]t is well established that trades under [a] 10b-5-1 plan do not raise a strong inference of scienter."); see also Koplyay, 2013 WL 6233908, at *6; In re IAC/InterActiveCorp Sec. Litig., 478 F. Supp. 2d 574, 604 (S.D.N.Y. 2007).[14] While the plan was entered into during the 23-month Class Period, CAC ¶ 184—a fact insufficient to plead motive, see In re Aratana Therapeutics Inc. Sec. Litig., 315 F. Supp. 3d 737, 764 (S.D.N.Y. 2018)—Plaintiff does not even attempt to plead facts indicating that Meury entered into the trading plan "'strategically' so as to capitalize on insider knowledge," as required. Lululemon, 14 F. Supp. 3d at 585.

B. The CAC Does Not Allege Strong Circumstantial Evidence of Fraudulent Intent Or Recklessness

Because the CAC fails to adequately plead motive, "the strength of the circumstantial allegations . . . of . . . recklessness or conscious misbehavior [must be] correspondingly greater." Koplyay, 2013 WL 6233908, at *7. However, the CAC's allegations of conscious misbehavior or recklessness, which overwhelmingly rely on information that was publicly available at the relevant time rather than particularized allegations of undisclosed data available to Allergan and reviewed by any specific Individual Defendant, do not meet this standard for several reasons.

[14] The CAC incorrectly alleges that Meury's February 14 sale was not made pursuant to a 10b5-1 plan. See Ex. 17.

First, where, as here, Plaintiff seeks to plead scienter by alleging that Defendants "knew or deliberately disregarded" certain facts, "they must specifically identify the reports or statements containing this information." Garber v. Legg Mason, Inc., 537 F. Supp. 2d 597, 615, 618 (S.D.N.Y. 2008). But the CAC fails to specifically (or even generally) identify a single undisclosed internal report or statement suggesting that Defendants knew or were reckless in not knowing about an alleged "definitive link"—and different from what Allegan already disclosed—between ALCL and Allergan's textured breast implants. See Koplyay, 2013 WL 6233908, at *8 (rejecting argument that foreknowledge is evidence of scienter where complaint did not reference "reports or statements" containing allegedly concealed information); City of Brockton, 540 F. Supp. at 473 (no strong inference of scienter where plaintiffs "do not plead that these individuals had access to particular, identified internal reports that would have alerted them to a deliberate" fraud). Nor does the CAC contain specific allegations about each of the Individual Defendants' knowledge, as opposed to the generic allegation that, "[b]ecause of their positions with the Company," all of them can be assumed to have had "access to material information" showing their statements were false, CAC ¶ 28, which is insufficient as a matter of law. See City of Brockton, 540 F. Supp. at 473.

Instead, the CAC overwhelmingly relies on publicly available information from before or during the Class Period that disclosed the very risks Plaintiff claims were omitted at that time. For example, Plaintiff alleges that Defendants knew or were reckless in not knowing about an alleged "definitive link" by pointing to unspecified "adverse event reports on MAUDE." CAC ¶¶ 118-20. But as the CAC admits, reports on MAUDE are "publicly available." Id. ¶ 48. This pleading approach of relying on sources that were publicly available at the time to plead that Defendants intentionally or recklessly misled investors concerning that information is plainly

insufficient to raise any inference, let alone a strong inference, of scienter. See In re Bank of Am. AIG Disclosure Sec. Litig., 980 F. Supp. 2d 564, 586 (S.D.N.Y. 2013) ("Several factors, including third party disclosure of relevant information, [defendant's] own disclosures, and [defendant's] apparent compliance with relevant regulatory provisions, support an inference against scienter that is far stronger than the competing inference that the plaintiffs' suggest.").[15]

Second, in an apparent attempt to suggest that Defendants knew or were reckless in not knowing about a purported "definitive link," Plaintiff points to Allergan's own BIA-ALCL research, presented by Dr. Stephanie Manson Brown at a 2019 FDA conference, and asserts that Allergan "reported ***shockingly high incidence rates***" of ALCL in certain textured implants. CAC ¶ 178. But the very document on which Plaintiff relies contradicts that allegation—her presentation stated that BIA-ALCL was "rare" and "uncommon." Ex. 34 at 6, 13. Similarly, while Plaintiff alleges that Allergan "admit[ted]" its ALCL incidence rates were "higher than those reported by any other manufacturer," CAC ¶ 178, those rates do not demonstrate a "definitive link" and, in any event, Plaintiff conveniently omits the remainder of Dr. Brown's statement, which indicates that this "may represent the effects of procedure, patient genetic predisposition, and/or environmental factors"—in other words it may have nothing to do with the

[15] To the extent Plaintiff baldly alleges that "the number of adverse event reports on MAUDE actually understates the extent of the problem," CAC ¶ 119, it has not alleged particularized facts indicating what the true extent of the problem was, let alone identified specific reports or statements indicating that anyone at Allergan knew about this information. Nor does Plaintiff provide particularized facts supporting its allegation that Allergan was intentionally "bury[ing]" evidence concerning ALCL because Allergan submitted "at least one case of possible BIA-ALCL" through an ASR. Id. ¶ 121. The article Plaintiff cites merely expresses disagreement with the way the FDA permitted manufacturers to report "ruptures and other injuries." Ex. 22 at 3 (cited CAC ¶¶ 57-58, 121 & nn.6-7, 43). Moreover, while Plaintiff takes issue with the reporting of a "possible" case of ALCL through an ASR, the source Plaintiff cites describes that the FDA expressly permitted the filing of ASRs. See supra Argument I.B.

implants themselves. Ex. 32 at 52 (cited CAC ¶ 178). Nor, more generally, does the research identify any information the Individual Defendants knew during the Class Period.

Third, while the CAC alleges that it was "foreseeabl[e]" Allergan's textured breast implants would be recalled from "certain markets," see CAC ¶ 10(iii), 127, 129, 131, 137, 139, 141, 143, 145, 147, 154, 156, 158, 161, 163, the CAC does not contain a "single allegation . . . that [the relevant notified body] ever explicitly warned defendants" that Allergan faced a risk of nonrenewal. Biovail, 615 F. Supp. 2d at 228. And, of course, merely relying on the subsequent non-renewal and recall request to plead that Defendants must have known before is improper fraud-by-hindsight. Id.; see also In re Bausch & Lomb, Inc. Sec. Litig., 592 F. Supp. 2d 323, 347, 350 (W.D.N.Y. 2008) (plaintiffs failed to show defendants "must have known" their contact lens solution would need to be withdrawn prior to the withdrawal).

Fourth, Plaintiff cannot raise a strong inference of scienter through the conclusory statements of the two CWs cited in the CAC: (1) a "Senior Project Manager for Allergan from June 2010 to November 2014"; and (2) "a Biological Research Associate III at Allergan from December 2014 to June 2017." CAC ¶¶ 29-30. The allegations based on these CWs suffer from numerous fatal flaws:

- Both CWs are low-level former employees who are not adequately alleged to have had positions likely to give them knowledge of any issues at a company-wide level. See Local No. 38 Int'l v. Am. Exp. Co., 724 F. Supp. 2d 447, 460 (S.D.N.Y. 2010) (no scienter where "many of the CWs were employed in rank-and-file positions" and "most of these employees had no access to aggregated data").[16]

- Neither is alleged to have "met the Individual Defendants, reported any concerns, received any instructions, or made any personal contact with them during the Class

[16] See also Wachovia, 753 F. Supp. 2d at 355 ("Coupling field office anecdotes with incriminating adverbs is not enough to raise an inference of scienter."); Cal. Pub. Emps.' Ret. Sys. v. Chubb Corp., 394 F.3d 126, 149 (3d Cir. 2004) ("Plaintiffs cite to low-level, locally sited former employees without alleging how or why such employees would have knowledge that expanded beyond" their positions.).

Period." Wachovia, 753 F. Supp. 2d at 352. Thus, the CWs cannot speak to the knowledge of Company management, as required to raise a strong inference of scienter. See Bettis, 2016 WL 7468194, at *10 (discounting allegation from CW who was in "no position to know what management did or did not know").

- CW1 was not even employed by Allergan during the Class Period and thus cannot speak to Defendants' knowledge during that time. See Malin v. XL Capital Ltd., 499 F. Supp. 2d 117, 141-42 (D. Conn. 2007) (CW allegations were "inadequate substantively" where "bulk of the information relayed by the CWs relates to the time prior" to Class Period and two CWs "left . . . prior to the start of the Class Period").

- In any event, CW1 is not alleged to have worked with breast implants and only states that "the Company began working on changes to the textured breast implants" before the Class Period, while conceding that s/he "was not told by the Company that these suggested changes were related to the link between textured implants and the development of ALCL." CAC ¶ 74. Therefore, even fully crediting these allegations, they do not raise any inference that the changes were made as a result of any ALCL link, let alone that Defendants intentionally misled investors on the subject. See Local No. 38, 724 F. Supp. at 460 ("anecdotes and conclusory statements of belief" by CWs "cannot form the basis for a finding of reckless disregard").

- CW2, who left Allergan long before the end of the Class Period, likewise asserts in a conclusory fashion that Allergan "did not study ALCL," but concedes "Allergan sent researchers and management to a number of conferences" where ALCL was discussed. CAC ¶¶ 95-96. Moreover, CW2's conclusory statement that Allergan "did not study ALCL" is contradicted by other allegations, which reference "Allergan's post-approval studies," own independent research, funding of external research, conducting of surgeon education meetings and webcasts, and partnerships with medical organizations to distribute BIA-ALCL educational materials. Id. ¶¶ 176-77; Ex. 13 at 7-8; Ex. 34 at 19-20. Similarly, CW2 alleges that Allergan shut down its Santa Barbara research facility in 2014, but concedes that it transferred five members of the breast implant research team to other facilities. CAC ¶ 97. Thus, nothing in CW2's allegations is inconsistent with Defendants' disclosures—which identified the possible ALCL link, the closure of the Santa Barbara facility, and Allergan's involvement in conferences—let alone establishes that Defendants' statements were knowingly false when made.

Finally, even if the CAC could be viewed as raising a weak inference of scienter—which it cannot—that inference is far from "cogent and compelling," Tellabs, 551 U.S. at 310, given the CAC's overwhelming reliance on publicly available information (including disclosures by Defendants) to state a claim. Instead, the far more likely inference is one of nonfraudulent intent: that Defendants (1) did not disclose there was a "definitive link" between ALCL and

textured implants because, as reflected in the sources cited in the CAC, none has been established, but (2) regularly disclosed and warned of a possible association between its implants and ALCL, (3) did not engage in any suspicious stock sales (or any sales at all for the majority of Individual Defendants), and (4) were surprised by the CE Mark nonrenewal and French recall request that was not based on new scientific data. Accordingly, the CAC fails to raise a strong inference of scienter and must be dismissed.

III. PLAINTIFF CANNOT PLEAD RELIANCE

The Court should dismiss Plaintiff's claims for the independent reason that the CAC does not and cannot plead that Plaintiff relied on any of the alleged misstatements or omissions, as the very information Plaintiff claims was omitted was in fact extensively disclosed by Allergan and others both before and throughout the Class Period. See supra Argument I.A.

It is well established that Plaintiff cannot plead reliance when the Defendants "explicitly disclosed the very . . . risks about which [Plaintiff] claim[s] to have been misled." Ashland Inc. v. Morgan Stanley & Co., 652 F.3d 333, 338 (2d Cir. 2011); see also Wilson v. Merrill Lynch & Co., 671 F.3d 120, 131-32 (2d Cir. 2011) (Defendant's "disclosures of its support bidding practices sufficed to preclude [Plaintiff's] claim that these practices were manipulative"). Moreover, given that Plaintiff relies almost exclusively on contemporaneous publicly available information to plead that Defendants made actionable omissions, as a matter of law it "cannot establish reasonable reliance" because "through minimal diligence, [it] should have discovered the conduct that constituted the alleged" fraud. In re UBS Auction Rate Sec. Litig., 2010 WL 2541166, at *22 (S.D.N.Y. June 10, 2010); see also Tanzanian Royalty Expl. Corp. v. Crede CG III, Ltd., 2019 WL 1368570, at *8 (S.D.N.Y. Mar. 26, 2019) (reliance unreasonable when "shareholder could have discovered the truth by 'investigat[ing] . . . already-disclosed' materials").

IV. PLAINTIFF FAILS TO PLEAD LOSS CAUSATION

The CAC should separately be dismissed because Plaintiff cannot plead that there was any disclosure correcting the alleged misstatements or omissions, and thus that its "losses were caused by the disclosure of the truth that Defendants had previously allegedly misrepresented." Biovail, 615 F. Supp. 2d at 229; see also Lululemon, 14 F. Supp. 3d at 587.

As an initial matter, Plaintiff does not even attempt to allege that the purportedly omitted information concerning the closing of the Santa Barbara facility, the alleged filing of one "possible" case of ALCL through an ASR, and unidentified consumer complaints, CAC ¶ 10, was ever "corrected," let alone that such (non-existent) correction caused a stock price decline.

With respect to the CAC's claim that Defendants failed to disclose the alleged "definitive link" between their textured breast implants and ALCL, the CAC asserts that Allergan's December 19, 2018 press release "stating that it would cease selling textured breast implants in Europe" due to ANSM's recall request "was the first time the Company acknowledged that its prior statements telling investors that its breast implants were not reported to be linked to ALCL in Europe were not accurate." Id. ¶¶ 165-66. The CAC then alleges that, after the ANSM recall request and Allergan's press release, Allergan's stock price declined. Id. ¶ 167. Putting aside that Plaintiff nowhere expressly alleges loss causation, Plaintiff's self-serving characterization of Allegan's press release is contradicted by that document itself: rather than acknowledging that there was a definitive link between ALCL and its implants, Allegan noted that (i) the recall was "not based on any new scientific evidence," (ii) ANSM has not "identified any immediate risk to the health of women with textured breast implants," and (iii) Allergan therefore "disagree[d]" with the recall and "stands behind the benefit/risk profile of [its] breast implant products." Ex. 25 (cited CAC ¶¶ 11, 165). Nothing in Allergan's press release—and nothing in the ANSM

recall request—"acknowledged" that there was a "definitive link" to ALCL or revealed that Defendants' prior statements not mentioning a "definitive link" were misleading.

Plaintiff's allegations are on all fours with those rejected by this Court in Biovail, which found that a complaint failed to allege a corrective disclosure based on the FDA's decision to reject a drug application:

> The all-but-inevitable decline in the price of Biovail's stock price following the company's announcement that the FDA had not approved the [drug] application . . . was caused by the agency's failure to approve the drug – not by any "corrective" disclosure of some prior untruth. Nothing in the . . . announcement that the FDA had declined to approve [the drug] "corrected" or otherwise revealed the "actual truth" behind any prior alleged misrepresentation by defendants, or otherwise tied the resulting stock price decline to any prior alleged fraud.

615 F. Supp. 2d at 229. Just as in Biovail, the CAC fails to identify any disclosure and concomitant price drop that corrected some prior untruth about a purported "definitive link" between the textured implants and ALCL, and therefore fails to plead loss causation.

V. PLAINTIFF'S CONTROL PERSON CLAIM SHOULD BE DISMISSED

Because Plaintiff fails to plead a primary violation of Section 10(b), the CAC's control person claim against Defendants under Section 20(a) must be dismissed. See Koplyay, 2013 WL 6233908, at *8; Bettis, 2016 WL 7468194, at *17. Additionally, for the reasons that the CAC fails to plead scienter, Plaintiff's Section 20(a) claim fails to plead that any Defendant was, in some meaningful sense, "a culpable participant" in the alleged fraud, as also required for Section 20(a) liability. See In re ShengdaTech, Inc. Sec. Litig., 2014 WL 3928606, at *10 (S.D.N.Y. Aug. 12, 2014) (collecting cases); Koplyay, 2013 WL 6233908, at *8.

CONCLUSION

For the foregoing reasons, the CAC should be dismissed with prejudice.

Dated: May 24, 2019
New York, New York

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